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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,622	02/19/2002	Wolfgang Daum	14005.01	5614
22865	7590	08/31/2004	EXAMINER	
ALTERA LAW GROUP, LLC 6500 CITY WEST PARKWAY SUITE 100 MINNEAPOLIS, MN 55344-7704			DAWSON, GLENN K	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/078,622

Applicant(s)

DAUM ET AL.

Examiner

Glenn K Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-23 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04-01-02, 06-27-02</u> | 6) <input type="checkbox"/> Other: ____ |

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification does not provide support for the limitation in claim 1 of the drug material being effective “only” when heated by exposure to an electromagnetic field and heat energy has heated the drug material. Any type of heating which heats up the drug material would suffice to activate the drug or cause its release.

Claim 9 recites a sending antenna is placed inside the implant using a catheter inserted through vessels, which was not recited in the specification.

In claim 16, the heating being “invasive” is not supported by the original specification.

Claim Objections

Claims 3 objected to because of the following informalities: Appropriate correction is required.

In claim 3, the phrase “where is substantially active” is missing words.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 15 positively recites that the implantable member is implanted in the body. That patient’s body is non-statutory subject matter.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13 and 15-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian-5304121.

Sahatjian discloses a drug delivery catheter having either or both of a balloon and/or stent coated with a drug material which when heated releases the drug to prevent restenosis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 10-12 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sahatjian-'121 in view of Diamantopoulos-EP 1 036 574.

Sahatjian discloses a drug delivery catheter having either or both of a balloon and/or stent coated with a drug material which when heated releases the drug to prevent restenosis. However, the heating of the coating is done by use of a heated or thermal balloon catheter. The examiner contends that even though not disclosed that the endoprosthesis coated with the drug material would be capable of being released if heated by an electromagnetic field. However, absent this finding, since Diamantopoulos discloses the use of electromagnetic fields to heat a stent, it would have been obvious to have used any known heating method to heat the stent (and by association the

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coating) and thereby release the drug, as this was shown to be an effective manner of non-invasively heating an implanted article.

Claims 1-8 and 10-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang-6379382 in view of Rosenthal, et al.-6524274, Diamantopoulos-'574 or Gunther-6238421.

Yang discloses a coated stent with drugs therein which are released over time. However, the use of electromagnetic fields to activate or release the drug is not disclosed. Rosenthal discloses that it was known to provide a coating with drugs therein having a melting point above body temperature which can be heated to cause the release of the drugs. The heating can be done by either a thermal catheter, or a local fiber optic device. Diamantopoulos and Günter disclose the use of electromagnetic fields to heat a stent. It would have been obvious to have used the magnetic fields taught by Diamantopoulos-'574 or Gunther-6238421 to heat the coated stent of Yang, as this was shown to be an effective manner of non-invasively heating an implanted article.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on 703-308-0858. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
21 August 2004